IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA

KING DRUG COMPANY OF FLORENCE, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1797
VISTA HEALTHPLAN, INC., et al., Plaintiffs, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-1833
APOTEX, INC., Plaintiff, v. CEPHALON, INC., et al., Defendants.	:	CIVIL ACTION No. 2:06-cv-2768
FEDERAL TRADE COMMISSION, Plaintiff, v. CEPHALON, INC., Defendant.	:	CIVIL ACTION No. 2:08-cv-2141

Goldberg, J. **January 28, 2015**

MEMORANDUM OPINION

Presently before me are several motions for summary judgment arising out of the standards recently articulated by the United States Supreme Court in Federal Trade Commission v. Actavis, Inc., 133 S. Ct. 2223 (2013). These motions are brought under the consolidated antitrust lawsuits referred to as the In re Modafinil Litigation, which centers around four "reverse-payment" settlement agreements between a pharmaceutical company and several generic drug manufacturers.[1]

Defendants argue that Actavis requires a plaintiff challenging a reverse-payment settlement on antitrust grounds to prove, as a threshold matter, that the reverse payment was both large and unjustified. Plaintiffs, Direct Purchasers and End Payors of Provigil, the Federal Trade Commission ("FTC"), and Apotex, Inc., dispute that Actavis requires some type of threshold burden. These Plaintiffs assert that, in any event, they have presented sufficient evidence of a large and unjustified reverse payment to survive summary judgment.

After careful consideration of the Actavis case and several recent district court opinions interpreting the standards set forth by the Supreme Court, I conclude that Actavis primarily instructs that the familiar antitrust rule of reason analysis be applied to cases challenging reverse-payment settlements. This analysis does not include a "threshold burden," as Defendants suggest. Rather, Plaintiffs must present evidence of a large reverse payment as part of their

[1] As detailed infra, these agreements were entered into by Defendant, Cephalon, Inc. ("Cephalon"), the brand-name manufacturer of Provigil, and the following Defendant generic drug manufacturers: Barr Pharmaceuticals, Inc. ("Barr"); Mylan Laboratories, Inc. and Mylan Pharmaceuticals, Inc. (collectively "Mylan"); Teva Pharmaceutical Industries, Ltd. and Teva Pharmaceuticals USA, Inc. (collectively "Teva"); and Ranbaxy Laboratories, Ltd. and Ranbaxy Pharmaceuticals, Inc. (collectively "Ranbaxy") (collectively referred to as the "Generic Defendants").

initial burden of demonstrating anticompetitive effects under the rule of reason. I further find that, as in other rule of reason cases, if Plaintiffs meet this standard, the burden shifts to Defendants to justify the reverse payment as procompetitive. If that occurs, Plaintiffs must then present sufficient evidence so as to raise a genuine dispute of material fact as to whether the reverse payment is unjustified or unexplained.

After considering the voluminous record in this case, I find that Plaintiffs have satisfied their burden of presenting evidence of anticompetitive effects, which includes a large reverse payment. I further find that there exists a genuine dispute of material fact that Defendants' procompetitive justifications are pretextual, allowing Plaintiffs to survive summary judgment on their Actavis claims. This Opinion sets forth the reasons for these conclusions.

I. FACTUAL AND PROCEDURAL BACKGROUND[2]

A. Administrative Framework

The Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, commonly known as the Hatch-Waxman Act, is designed to encourage the development and marketing of generic versions of approved drugs. It allows generic manufacturers to file an Abbreviated New Drug Application ("ANDA") when seeking approval from the Food and Drug Administration ("FDA") to market a generic version of an approved drug. An ANDA filer is able to adopt the safety and efficacy studies that the FDA previously approved in connection with a bioequivalent brand-name drug's New Drug Application ("NDA"). See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc., 527 F.3d 1278, 1282 (Fed. Cir. 2008).

[2] All facts are undisputed, unless otherwise noted, and disputed facts are viewed in the light most favorable to Plaintiffs—the non-moving parties. See Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 256 (1986).

A generic manufacturer seeking approval of an ANDA must demonstrate that the generic formulation and the approved brand-name drug share the same active ingredients and are bioequivalent. Additionally, ANDA filers must submit one of four certifications addressing any and all patents covering the brand-name drug, certifying either: (1) that the relevant patent information has not been filed with the FDA; (2) that such patent has expired; (3) the date that such patent will expire; or (4) "that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted." Id. at 1282-83 (quoting 21 U.S.C. § 355(j)(2)(A)(vii)). "If a generic drug company seeks to market a generic version of a listed drug before the expiration of the Orange-Book-listed patents[3] covering that drug, it must file a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV), i.e. a 'Paragraph IV certification.'" Id. at 1283 (citing Eli Lilly & Co. v. Medtronic, Inc., 496 U.S. 661, 676 (1990)).

Paragraph IV filers are required to submit notice of the filing to the patent owner and the NDA holder, and must set forth a detailed statement of the basis for the assertion that the patent is invalid or will not be infringed. Id. Filing a Paragraph IV ANDA constitutes an act of patent infringement, often prompting the patent holder to file a lawsuit. However, as an incentive to generic companies to challenge weak patents, the first applicant to file an ANDA with a Paragraph IV certification is entitled to a 180-day period of exclusivity for its generic drug, beginning on the first day it markets its drug commercially. Actavis, 133 S. Ct. at 2228-29.

When a patent holder files an infringement lawsuit within forty-five days of a Paragraph IV ANDA filing, the FDA is barred from approving the generic company's ANDA for a period of thirty months. 21 U.S.C. § 355(j)(5)(B)(iii). If the case is resolved during the thirty-month

[3] The FDA publishes a list of all patents covering a drug under which a claim of patent infringement could reasonably be asserted in the "Approved Drug Products with Therapeutic Equivalence Evaluations" publication, also known as the Orange Book. Caraco Pharm. Labs., Ltd., 527 F.3d at 1282.

stay, the FDA will take action on the ANDA consistent with the court's judgment. Actavis, 133 S. Ct. at 2228. If the case is still ongoing at the end of the thirty-month period, the FDA may approve the ANDA, at which point the generic company will have to decide whether to sell its drug "at risk" of incurring damages should the infringement case result in a judgment favorable to the patent holder. Id.

B. Factual History

Cephalon was issued U.S. Patent No. 5,618,845 ("the '845 patent") in April 1997, covering specific formulations of modafinil, the active pharmaceutical ingredient ("API") in Provigil. (CBT SUF ¶ 2.) Modafinil is a wakefulness-promoting agent used to treat narcolepsy and other sleep disorders. (Letter Decl., Ex. 1.) The FDA approved Cephalon's NDA for Provigil on December 24, 1998. In 2002, Cephalon was granted a reissue patent on modafinil, U.S. Patent No. RE 37,516 ("the RE '516 patent"), which was scheduled to expire October 6, 2014. However, as a result of studying Provigil's effects on children, Cephalon also received an additional six months of pediatric exclusivity on Provigil, extending Cephalon's exclusivity period through April 6, 2015. (CBT SUF ¶¶ 1-5.)

The Generic Defendants each filed a separate Paragraph IV ANDA with the FDA on December 24, 2002, the first date on which ANDAs were able to be filed, seeking to market a generic version of Provigil. Because each of the Generic Defendants filed ANDAs on the first possible day, all were eligible to share the 180-day exclusivity of a first-filer. Cephalon filed suit against the Generic Defendants for patent infringement on March 28, 2003. (Id. at ¶¶ 7-10.) In December 2004, the Generic Defendants moved to amend their respective pleadings, asserting that Cephalon had made material representations and omissions to the PTO, including that the

named inventors did not invent the modafinil composition covered by the RE '516 patent.[4] (Pls.' Comb. SUF ¶ 7.)

The litigation between Cephalon and the Generic Defendants ultimately settled between December 2005 and February 2006, while motions for summary judgment were pending. All of the settlement agreements included a provision where Cephalon granted the Generic Defendants a license to market their generic modafinil products on a "date certain"—the later of October 6, 2011, or, if Provigil obtained a pediatric extension of the RE '516 patent, April 6, 2012. The settlement agreements also provided that the Generic Defendants could enter the market earlier than the date certain if: (1) Cephalon licensed any other generic manufacturer to market generic modafinil prior to that date; (2) another generic decided to launch "at risk"; or (3) if a judgment declared that generic modafinil may be sold without infringing the RE '516 patent. (CBT SUF ¶¶ 11, 14-15, 23-24, 31-32, 49-50.) Each of the settlement agreements included provisions and/or were signed alongside various additional agreements whereby Cephalon paid the Generic Defendants (and associates of the Generic Defendants) a total of approximately $300 million. (See CBT Mot., Exs. 8-11, 13, 16-19.) These transactions are explored in greater detail herein.

1. The Teva Settlement Agreement

Cephalon entered into a settlement agreement with Teva on December 8, 2005. In addition to the licensing provisions allowing Teva to begin selling its generic modafinil product on a date certain, Cephalon also agreed to make royalty payments to Teva in exchange for a worldwide license to Teva's modafinil-related intellectual property ("IP"). The royalty payments

[4] The same facts and defenses raised by the Generic Defendants in their Paragraph IV litigation were later presented to this Court in the Apotex v. Cephalon patent litigation, resulting in the RE '516 patent being declared invalid and unenforceable. (See Pls.' Comb. SUF ¶¶ 8-28); Apotex, Inc. v. Cephalon, Inc., 2011 WL 6090696 (E.D. Pa. Nov. 7, 2011) aff'd, 500 Fed. Appx. 959 (Fed. Cir. 2013).

included lump sum payments at certain sales benchmarks and a three percent royalty on all worldwide net sales of all Cephalon Modafinil Product until either the licensed patents expired or the total royalty payments reached a maximum of $125 million. (Id. at ¶¶ 12-17.) Cephalon also entered into an API supply agreement with Teva, whereby Teva agreed to manufacture and supply Cephalon with 10,000 kg per year of modafinil API for a five-year period at the following prices: $650/kg in the first year, and $500/kg to $600/kg in subsequent years. (Id. at ¶¶ 18-20.) Cephalon and Teva further agreed to settle pending patent litigation related to the modafinil patent in the United Kingdom in exchange for Cephalon paying Teva 2.1 million British pounds and 2.5 million Euros. Finally, Cephalon agreed to appoint Teva UK Limited as the exclusive distributor of Cephalon modafinil products in the United Kingdom for five years, that Cephalon would provide Teva with modafinil at eighty percent of Teva's resale price, and Cephalon would pay Teva 2.5 million Euros. Pursuant to this settlement agreement, Cephalon has paid Teva in excess of $164 million. (Pls.' Comb. SUF ¶ 153, 158.)

2. The Ranbaxy Settlement Agreement

Cephalon and Ranbaxy settled their patent litigation on December 22, 2005. In addition to the license for date-certain entry, Cephalon made a one-time $2 million payment to Ranbaxy for avoidance of litigation costs. Cephalon also entered into an IP licensing agreement with Ranbaxy, whereby Cephalon was granted a non-exclusive worldwide license to Ranbaxy's IP involving formulations of modafinil in exchange for $1 million up front and certain milestone payments up to a maximum of $5 million. Ranbaxy and Cephalon also entered into an API supply agreement, under which Cephalon agreed to purchase 15,000 kg per year of modafinil API from Ranbaxy, and to pay Ranbaxy $550/kg in the first year, $500/kg in the second year, $445/kg in the third year, $385/kg in the fourth year, and $325/kg in the fifth year. (Id. at ¶¶ 25-

28; Pls.' Comb. SUF ¶ 163.) The API that Cephalon purchased from Ranbaxy was not manufactured by Ranbaxy, but was instead manufactured by a third party, Matrix. Ranbaxy purchased the API from Matrix and sold it to Cephalon at a mark-up of close to seventy percent. Although Cephalon had pledged to pay Ranbaxy $40 million through these payments, the Ranbaxy API agreement was terminated in 2009 in exchange for a buyout. As a result, these agreements resulted in payments from Cephalon to Ranbaxy in an amount exceeding $25 million. (Pls.' Comb. SUF ¶¶ 163, 169, 250.)

3. The Mylan Settlement Agreement

On January 9, 2006, Cephalon and Mylan entered into a settlement agreement, which provided for date-certain entry, and a $2 million payment to Mylan for avoided litigation costs. (Pls.' Comb. SUF ¶ 173.)

On that same date, Mylan Technologies, Inc. and Cephalon entered into a Collaboration Agreement whereby Cephalon engaged Mylan Technologies to conduct a research program on the feasibility of developing a transdermal patch that would deliver naltrexone[5] to patients. Cephalon was then provided an option to engage Mylan Technologies for further co-development and an exclusive license to develop, manufacture and sell any resulting product, with royalty and milestone payments due to Mylan. Pursuant to the Collaboration Agreement, Cephalon paid Mylan Technologies $10 million up front. The Agreement further provided for a payment of $15 million to Mylan upon Cephalon's receipt of a "positive" feasibility report. Cephalon also agreed to make royalty payments to Mylan Technologies based on product sales, ranging from twelve to twenty percent. Cephalon ultimately terminated the Naltrexone Agreement effective February 5, 2009. (Mylan SUF ¶¶ 22, 25-27, 35, 37-40, 42-43, 50, 52.)

[5] Naltrexone is a drug used to treat alcoholism. (Mylan SUF ¶ 37.)

Finally, on the same date that the patent litigation was settled and Cephalon and Mylan Technologies Inc. entered into the Naltrexone Collaboration Agreement, Cephalon and Mylan Laboratories Inc. also entered into an Option and Exclusivity Agreement regarding a seven-day transdermal fentanyl[6] patch. The Agreement provided Cephalon an exclusive option to obtain certain rights and licenses with respect to the fentanyl patch. Cephalon purchased an exclusive option for $10 million on February 7, 2006. Cephalon was provided several months to determine whether it wished to exercise its option. Ultimately, Cephalon exercised its option and entered into a Fentanyl Collaboration, License and Supply Agreement on October 16, 2006, making an additional $10 million payment to Mylan. Cephalon terminated the Collaboration Agreement effective March 6, 2009. (Id. at ¶¶ 52, 54, 57-58, 60-67, 71.)

These agreements[7] resulted in a total of approximately $48 million in payments from Cephalon to Mylan Pharmaceuticals Inc., Mylan Technologies, Inc. and Mylan Laboratories Inc. (Pls.' Comb. SUF ¶ 176.)

4. Barr Settlement Agreement

Cephalon and Barr entered into a settlement agreement effective February 1, 2006, providing a license to Barr to begin selling generic modafinil on the date certain. On the same date, Cephalon and Barr also entered into a modafinil license and supply agreement, as well as a

[6] Fentanyl is a pain medication primarily used with cancer patients. (Id. at ¶ 53.)

[7] Defendants argue that the Collaboration Agreement and Option and Exclusivity Agreement (described infra) cannot be characterized as part of the settlement agreement. However, Plaintiffs have presented sufficient evidence for a reasonable jury to determine that the three contracts were separate pieces of one cohesive agreement, and that the product development agreements were necessary to the settlement. (See Letter Decl., Ex. 120 (Cephalon emailing the three agreements to Mylan for signature on the same date, insisting that all three be signed prior to a press release scheduled for the following morning); Bazerman Exp. Rep., Apr. 21, 2011, ¶ 40 ("the Cephalon/Mylan agreements would not have occurred at the same time if the contemporaneous business transactions were independent of the patent settlement").)

separate settlement agreement for litigation over Cephalon's drug Actiq, a pain medication. Cephalon and Barr also entered into an Actiq licensing and supply agreement. Additionally, Cephalon entered into a modafinil API supply agreement with ChemAgis, Barr's modafinil partner, also effective February 1, 2006. Finally, on the same date, Cephalon and Perrigo Israel Pharmaceuticals Ltd., an affiliate of ChemAgis, entered into a product development Collaboration Agreement. (Id. at ¶¶ 181-86.) These Agreements are further described herein.

Under the Cephalon-Barr settlement agreement, Cephalon agreed to purchase from Barr a patent license related to modafinil for $1 million and to pay Barr $2 million for avoided litigation costs. Cephalon also agreed to purchase 10,000 kg per year of modafinil API from ChemAgis for a period of five years. Pursuant to this agreement, even if Cephalon ordered less than 10,000 kg per year, Cephalon was required to purchase the full amount from ChemAgis. The agreed upon prices for the modafinil API were $500/kg in the first year, $450/kg in the second year, and $400/kg in the third through fifth years. Barr and ChemAgis agreed that Barr would receive fifty percent of all profits arising out of the API supply agreement. (Id. at ¶¶ 187, 272.)

As for Perrigo, Cephalon agreed to collaborate on the potential development of two drugs in exchange for Cephalon making certain milestone payments to Perrigo. All six agreements were discussed in a series of meetings between Cephalon, Barr and Chemagis. Counsel for Cephalon held the signature pages for these six agreements in escrow until they had all been submitted.[8] Cephalon made payments in amounts exceeding $63 million pursuant to these agreements. (Id. at ¶¶ 191-94, 263, 267-68.)

[8] Although the ChemAgis supply agreement was signed as a separate agreement, it had originally been included within the settlement agreement between Cephalon and Barr. The API supply agreement was excised and written separately pursuant to a change requested by Barr. (Pls.' Comb. SUF ¶¶ 270-71.) In light of this evidence and the simultaneous signatures required by the

C. Plaintiffs' Claims and the Motions for Summary Judgment

Plaintiffs assert that at the time these settlement agreements were executed, both Cephalon and the Generic Defendants knew that the RE '516 patent was invalid and unenforceable. Plaintiffs claim that, despite this knowledge, Cephalon and the Generic Defendants agreed to share Cephalon's monopoly profits in exchange for the Generic Defendants agreeing to drop their challenges to the RE '516 patent and stay off of the market until 2012. Accordingly, Plaintiffs argue that the four agreements described above were illegal reverse-payment settlements under Actavis.

In their motions for summary judgment, Defendants urge that, under Actavis, Plaintiffs must first meet a threshold burden establishing that Cephalon made a large and unjustified reverse payment to the Generic Defendants at the time of settlement. Defendants argue that they are entitled to a judgment as a matter of law because Plaintiffs cannot meet this "threshold burden." Plaintiffs respond that Actavis does not mandate any type of threshold burden, but rather instructs that a burden-shifting rule of reason analysis applies. Plaintiffs further assert that, even if they are required to demonstrate a large and unjustified reverse payment as a "threshold" matter, sufficient evidence exists on these issues to present to a fact finder.

II. STANDARD OF REVIEW

A party moving for summary judgment bears the initial burden of demonstrating that there are no genuine issues of material fact and that judgment is appropriate as a matter of law. FED. R. CIV. P. 56(a); Celotex Corp. v. Catrett, 477 U.S. 317, 323 (1986). Once a properly supported motion for summary judgment has been made, the burden shifts to the non-moving party, who must set forth specific facts showing that there is a genuine issue of material fact for

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parties, a reasonable jury could find that the ChemAgis and Perrigo agreements were necessary parts of the settlement agreement between Cephalon and Barr.

trial. Anderson v. Liberty Lobby, Inc., 477 U.S. 242, 250 (1986). An issue is "genuine" if a reasonable jury could rule in favor of the non-moving party based on the evidence presented. Kaucher v. Cnty. of Bucks, 455 F.3d 418, 423 (3d Cir. 2006). The non-moving party cannot avert summary judgment with speculation or conclusory allegations, but rather must cite to the record. Ridgewood Bd. of Educ. v. N.E. for M.E., 172 F.3d 238, 252 (3d Cir. 1999); FED. R. CIV. P. 56(c). On a motion for summary judgment, the court considers the evidence in the light most favorable to the non-moving party. Anderson, 477 U.S. at 256.[9]

III. DISCUSSION

A. What is the Appropriate Standard for Establishing Liability under *Actavis*?

1. *Federal Trade Commission v. Actavis, Inc.*

In Actavis, the United States Supreme Court considered the antitrust implications of what is commonly referred to as a reverse-payment settlement. This type of settlement typically occurs between a brand-name drug manufacturer (the patent holder) and an alleged generic infringer. Under these agreements, the patent holder pays the alleged infringer a substantial amount of money in exchange for the generic agreeing to drop the patent challenge and stay off of the market for a period of time, which has been characterized as anticompetitive conduct.

[9] Cephalon, Barr and Teva suggest that there exists a "special," heightened standard of review for motions for summary judgment in the antitrust context. The cases that these Defendants cite refer to the limited inferences that may be drawn from ambiguous, circumstantial evidence in establishing concerted action, and that summary judgment may not be thwarted by economically senseless theories. See Eastman Kodak Co. v. Image Tech. Svc., Inc., 504 U.S. 451, 468-69 (1992); Matsushita Elec. Indus. Co., Ltd. v. Zenith Radio Corp., 475 U.S. 574, 587-88 (1986); Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 73 (3d Cir. 2010); see also In re Flat Glass Antitrust Litig., 385 F.3d 350, 357-58 (3d Cir. 2004). Plaintiffs have presented direct evidence of concerted action through the settlement agreements between Cephalon and each of the Generic Defendants, and Defendants have not challenged Plaintiffs' ability to meet the concerted action requirement on these claims. Furthermore, the Supreme Court and United States Court of Appeals for the Third Circuit have made clear that "[t]he traditional summary judgment standard applies with equal force in antitrust cases[.]" Alvord-Polk, Inc. v. F. Schumacher & Co., 37 F.3d 996, 1001 (3d Cir. 1994) (citing Eastman Kodak, 504 U.S. at 468).

These reverse-payment settlements arise almost exclusively within the context of pharmaceutical drug regulation, specifically the Hatch-Waxman Act. Actavis, 133 S. Ct. at 2227-28.

In Actavis, Solvay Pharmaceuticals was the patent holder of the brand-name drug, AndroGel. Actavis, Inc. and Paddock Laboratories each filed ANDAs for a generic drug modeled after AndroGel, certifying that Solvay's patent was invalid and not infringed by their generic products. Id. at 2229. Patent litigation ensued and eventually settled, with Solvay paying each of the generics millions of dollars[10] in exchange for their agreement to stay off of the market until 2015—sixty-five months prior to the expiration of Solvay's patent. Id. The FTC sued all parties to the settlement agreements, alleging that they had unlawfully agreed to keep generic competition off of the market and share Solvay's monopoly profits in violation of the antitrust laws. Id. at 2230.

Prior to the Supreme Court's ruling in Actavis, several circuit courts had held that, absent sham litigation or fraud in obtaining the patent, reverse-payment settlements allowing for entry of a generic prior to the expiration of the brand-name patent were essentially immune from antitrust liability. These opinions were based on the premise that settlements that did not grant the patent holder any rights outside of the exclusionary bounds of the patent could not be subject to antitrust liability. See e.g., F.T.C. v. Watson Pharms., Inc., 677 F.3d 1298 (11th Cir. 2012) (rev'd, Actavis, 133 S. Ct. 2223).

Finding that the scope of the patent test did not end the inquiry, the Supreme Court held that reverse-payment settlements that allow for generic entry prior to the expiration of a patent may still be subject to antitrust scrutiny under the rule of reason because "[t]he patent . . . may or

[10] Paddock was paid $12 million; Par Pharmaceuticals, which joined forces with Paddock, was paid $60 million; and Actavis was paid $19-$30 million annually for a total of nine years. Id. at 2229.

may not be valid, and may or may not be infringed." Id. at 2230-31, 2237. Actavis listed five factors that led the Court to conclude a rule of reason analysis is appropriate: (1) reverse-payment settlements have the "potential for genuine adverse effects on competition"; (2) the anticompetitive consequences will sometimes prove unjustified; (3) patent holders often possess market power; (4) the size of the settlement can often indicate a patent holder's belief in the strength or weakness of its patent; and (5) the risk of antitrust scrutiny does not prevent litigants from settling. Id. at 2234-37.

2. The Rule of Reason

The standard rule of reason burden-shifting analysis applied in many antitrust cases has remained relatively unchanged for nearly a century. See United States v. Brown Univ. in Providence in State of R.I., 5 F.3d 658, 668 n.8 (3d Cir. 1993) (remarking that the rule of reason analysis has largely remained unchanged since it was first defined in Chicago Board of Trade v. United States, 246 U.S. 231, 238 (1918)). "The rule of reason requires the fact-finder to 'weigh [ ] all of the circumstances of a case in deciding whether a restrictive practice should be prohibited as imposing an unreasonable restraint on competition.'" Id. at 668 (quoting Continental T.V., Inc. v. GTE Sylvania Inc., 433 U.S. 36, 49 (1977)).

"The plaintiff bears an initial burden under the rule of reason of showing that the alleged combination or agreement produced adverse, anti-competitive effects within the relevant product and geographic markets." Id. (citing Tunis Bros. Co. v. Ford Motor Co., 952 F.2d 715, 722 (3d Cir. 1991)). A plaintiff can satisfy this burden by demonstrating either "actual anticompetitive effects, such as reduction of output, increase in price, [ ] deterioration in quality of goods or services[,]" or a plaintiff can satisfy its burden by establishing that the defendant possesses

market power—"the ability to raise prices above those that would prevail in a competitive market." Id. (citations omitted).

If the plaintiff establishes adequate evidence of anticompetitive effects and/or market power, the burden shifts to the defendant "to show that the challenged conduct promotes a sufficiently pro-competitive objective." Id. at 669. The plaintiff then has the opportunity to rebut the defendant's procompetitive justification by demonstrating that the defendant's conduct was not fairly necessary to achieve the procompetitive objective. Id. The fact-finder then weighs all of the effects and circumstances of the case and determines if the agreement is, on balance, anticompetitive. Pa. Dental Ass'n v. Med. Svc. Ass'n of Pa., 745 F.2d 248, 255 (3d Cir. 1984) (citing Chicago Board of Trade, 246 U.S. at 238). Under the rule of reason, "[t]he true test of legality is whether the restraint imposed is such as merely regulates and perhaps thereby promotes competition or whether it is such as may suppress or even destroy competition." Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 75 (3d Cir. 2010) (quoting Orson, Inc. v. Miramax Film Corp., 79 F.3d 1358, 1368 (3d Cir. 1996)).

3. Does *Actavis* Alter the Standard Rule of Reason Analysis?

The Actavis opinion makes clear that a rule of reason analysis must be applied to antitrust cases challenging a reverse-payment settlement. The specific contours of the rule of reason analysis to be applied under Actavis are not, however, well-defined, with the Supreme Court "leav[ing] to the lower courts the structuring of the present rule-of-reason antitrust analysis." Actavis, 133 S. Ct. at 2238. Actavis emphasizes that it is concerned with reverse-payment settlements bringing about a specific anticompetitive harm—the sharing of monopoly profits between a patent holder and a patent challenger in order "to avoid the risk of patent invalidation or a finding of noninfringement." Id. at 2236-37. To that end, Actavis states numerous times

that the risk of anticompetitive consequences is particularly pronounced where the reverse payment is "large and unjustified." See id. at 2237 ("a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects"). "[T]he likelihood of a reverse payment bringing about anticompetitive effects depends upon its size, its scale in relation to the payor's anticipated future litigation costs, its independence from other services for which it might represent payment, and the lack of any other convincing justification." Id.

The phrase "threshold burden" does not appear anywhere in Actavis. Nonetheless, Defendants urge that Plaintiffs must establish that the reverse payment is both large and unjustified as a threshold matter, and failure to meet this burden prohibits analysis under the rule of reason.[11] Defendants garner support for this interpretation from Chief Justice Roberts' dissent in Actavis and three district courts opinions that seem to have identified "large and unjustified" as hurtles the plaintiff must clear prior to a rule of reason analysis.

In his dissent in Actavis, Chief Justice Roberts states, "According to the majority, if a patent holder settles litigation by paying an alleged infringer a 'large and unjustified' payment, in exchange for having the alleged infringer honor the patent, a court should employ the antitrust rule of reason to determine whether the settlement violates antitrust law." Id. at 2239 (Roberts, J., dissenting). Defendants argue that this statement clearly dictates that a "large and unjustified" analysis must occur prior to application of the rule of reason. However, this alleged "threshold burden" standard is the dissent's interpretation of the majority ruling and is not found in the majority opinion. Nonetheless, Defendants press that the "threshold burden" requirement also finds support in subsequent district court opinions interpreting Actavis. See In re Lamictal

[11] I note that at oral argument, Barr acknowledged that a showing of large and unjustified may be part of Plaintiffs' initial burden under the rule of reason. In any event, Barr argued that Plaintiffs have failed to meet their burden, regardless of whether or not it is presented as a "threshold burden" prior to the application of the rule of reason. (Oral Arg. Tr., pp. 16-19.)

Direct Purchaser Antitrust Litigation, 18 F. Supp. 3d 560 (D.N.J. 2014); In re Loestrin 24 Fe Antitrust Litig., 2014 WL 4368924 (D.R.I. Sept. 4, 2014); In re Nexium (Esomeprazole) Antitrust Litigation, 2014 WL 4370333 (D. Mass. Sept. 4, 2014).

In re Lamictal largely focuses on whether a settlement exchanging non-monetary consideration may constitute a reverse-payment settlement. In dicta, the court noted that Actavis appears to require a three-step analysis: first, determine whether there is a reverse payment; second, determine if the reverse payment is large and unjustified; and third, apply the rule of reason. In re Lamictal, 18 F. Supp. 3d at 565; see also In re Loestrin, 2014 WL 4368924 (adopting the three-step approach used in In re Lamictal). Despite advocating this three-part test, the district court noted that "the Supreme Court's concern about a settlement size appears both in Step Two and Step Three[,]" which might indicate that "Steps One and Two are not preliminary steps, but rather part of a broad, open ended balancing" under the rule of reason. In re Lamictal, 18 F. Supp. 3d at 566.

Similarly, In re Nexium opines that the proper standard for a claim under Actavis requires plaintiffs to first prove that the settlement included a large and unjustified payment to the alleged patent infringer. Then, the defendants are given the opportunity to show that the payment was justified by a procompetitive objective. If the defendants provide a procompetitive justification, "the burden shifts back to the [p]laintiffs to establish, under the rule of reason, that the settlement is nevertheless anticompetitive on balance." In re Nexium, 2014 WL 4370333, at *23. Based upon my reading of this case, it is unclear whether "large and unjustified" is a threshold burden on the plaintiffs, analyzed separately from the rule of reason, or whether it is part of the plaintiff's initial burden under the rule of reason. In any event, the end result

under In re Nexium appears to be the same—if Plaintiffs do not establish that the payment is large and unjustified, the antitrust analysis ends.

Plaintiffs present two alternative interpretations of the parties' burdens under Actavis. The FTC and Apotex agree that Plaintiffs must establish, under the first step of the rule of reason analysis, that the payments were large.[12] (See FTC's Resp., p. 6 (describing its initial burden under the rule of reason as demonstrating "that Cephalon possessed market power and made a payment to a generic challenger sufficient to induce the generic challenger to abandon its claim"); Apotex's Resp., p. 17 ("Defendants' motions should be denied because Apotex has met the initial burden under Actavis of demonstrating a large reverse payment").) The remaining Plaintiffs, however, assert that their burden under Actavis is the same burden they would face in any other rule of reason case: demonstrating actual anticompetitive effects, such as reduction of output, increase in price and deterioration in quality of goods or services, or by establishing that Cephalon possessed market power. All Plaintiffs agree that Defendants bear the burden of justifying the reverse-payment settlement, which Plaintiffs may then rebut. I am unaware of any post-Actavis cases adopting either of the approaches suggested by Plaintiffs. However, after careful examination of applicable precedent, I conclude that the approach suggested by the FTC and Apotex most closely follows the teachings of Actavis.

Most telling is the fact that, nowhere in the Actavis opinion does the Supreme Court state that plaintiffs bear a "threshold burden" of demonstrating that the reverse payment was large and

[12] The private Plaintiffs argue that even if they do not satisfy their burden under Actavis, summary judgment may not be granted on their challenges to the settlement agreements due to their allegations of fraud in the procurement of Cephalon's patent. They assert that proof of Walker Process fraud renders the settlement agreements per se violations of the Sherman Act, and thus, evidence of fraud is sufficient to deny summary judgment. The Generic Defendants respond that they may not be held liable under the antitrust laws for Cephalon's fraud. I need not address this issue at this time because, as detailed infra, I find that Plaintiffs have provided sufficient evidence to survive summary judgment under Actavis.

unjustified. While the terms "large" and "unjustified" are used several times in the opinion, and certainly appear to be important, perhaps the clearest guidance given to trial courts is that antitrust cases involving reverse-payment settlements must be analyzed under the rule of reason. The question then becomes: when structuring a reverse-payment settlement case, where do the "large and unjustified" considerations belong within the rule of reason analysis?

As noted above, under a standard rule of reason analysis, the plaintiff bears the initial burden of demonstrating that "the alleged combination or agreement produced adverse, anti-competitive effects within the relevant product and geographic markets." Brown Univ., 5 F.3d at 668. The plaintiff can meet this burden by demonstrating actual anticompetitive effects or by establishing that the defendant possesses market power. Id. Actavis notes that both the likelihood of anticompetitive harm and the probability that the patent holder possesses market power increase as the size of the reverse payment increases. Actavis 133 S. Ct. at 2235-36. For example, the Court remarks that a large payment can provide strong evidence of the relevant anticompetitive harm—"that the patentee seeks to induce the generic challenger to abandon its claim with a share of its monopoly profits that would otherwise be lost in the competitive market." Id. at 2235. Importantly, Actavis instructs that "the size of the payment from a branded drug manufacturer to a prospective generic is itself a strong indicator of [market] power." Id. at 2236 (citation omitted) (emphasis added). These statements indicate that evidence of a large payment is required for a plaintiff to satisfy its initial burden of demonstrating anticompetitive effects under the Actavis rule of reason analysis. See also id. at 2237 ("the likelihood of a reverse payment bringing about anticompetitive effects depends upon its size . . .").

Next, I must determine which party bears the burden of addressing potential justifications for the reverse payment under Actavis. In explaining why antitrust scrutiny of reverse-payment settlements is appropriate, the Court noted that, at least sometimes, the anticompetitive consequences these settlements may bring about will "prove unjustified." Id. at 2235-36. After discussing potential legitimate, procompetitive reasons that may justify a large reverse-payment settlement, the Court states that "[a]n antitrust defendant may show in the antitrust proceeding that legitimate justifications are present, thereby explaining the presence of the challenged term and showing the lawfulness of that term under the rule of reason." Id. at 2236. In making this statement, the Supreme Court cited to Federal Trade Commission v. Indiana Federation of Dentists, 476 U.S. 447, 459 (1986), which analyzed the defendant's burden of proving procompetitive effects under the rule of reason. The Actavis Court also cited to an antitrust treatise, discussing a defendant's burden to provide evidence of procompetitive justifications under the rule of reason. See 7 Phillip E. Areeda & Herbert Hovenkamp, Antitrust Law: An Analysis of Antitrust Principles and Their Application ¶¶ 1504a-1504b, at 401-04 (3d ed. 2010) ("Areeda & Hovenkamp"). In summarizing its decision, the Actavis Court notes that "a reverse payment, where large and unjustified, can bring with it the risk of significant anticompetitive effects; [and] one who makes such a payment may be unable to explain and to justify it[.]" Id. at 2237.

Under a standard rule of reason analysis, after a plaintiff establishes that an agreement has brought about anticompetitive effects, the burden shifts to the defendant to show that the challenged conduct promotes a sufficiently procompetitive objective—in other words, to justify the conduct. Brown Univ., 5 F.3d at 669; 7 Areeda & Hovenkamp ¶ 1504a, pp. 401-02 (under rule of reason "we look to the defendant, with its knowledge of its own situation, to identify the

possible justifications for its conduct"). Synthesizing this precedent with the Court's statements in Actavis, I find that whether or not the reverse payment is unjustified or unexplained is examined under the standard rule of reason burden-shifting framework, with the defendant bearing the burden of providing evidence that the reverse payment is justified by procompetitive considerations.

Lastly, if the defendant presents sufficient evidence of procompetitive justifications, the plaintiff must then rebut those justifications and establish that the "restraint is not reasonably necessary to achieve the stated objective." Race Tires Am., Inc. v. Hoosier Racing Tire Corp., 614 F.3d 57, 75 (3d Cir. 2010) ("The plaintiff then must demonstrate that the restraint itself is not reasonably necessary to achieve the stated objective"); Brown Univ., 5 F.3d at 669 (same). A plaintiff must raise a genuine dispute of material fact as to the defendant's justifications because Actavis indicates that where reverse payments reflect "traditional settlement considerations, such as avoided litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement." 133 S. Ct. at 2236. If the plaintiff provides evidence to rebut the defendant's justifications, the fact-finder will then weigh the anticompetitive and procompetitive effects, as in other rule of reason cases.

Defendants disagree with this framework and argue that placing the burden of justifying the payment on them creates a presumption of illegality that was rejected in Actavis. I disagree. In Actavis, the Court rejected the FTC's position that reverse-payment settlements should receive enhanced scrutiny under a "quick-look" approach. This approach is an intermediary standard, applied where "no elaborate industry analysis is required to demonstrate the anticompetitive character of an inherently suspect restraint." Brown Univ., 5 F.3d at 669

(quoting Nat'l Collegiate Athletic Ass'n v. Bd. of Regents of Univ. of Okl., 468 U.S. 85, 109 (1984)) (quotation marks omitted). Under a quick-look analysis, anticompetitive harm is assumed, and the burden is immediately placed on the defendant to justify the conduct. Id. Failure to provide a legitimate justification results in antitrust liability, but if the defendant provides a sound justification, the court weighs "the overall reasonableness of the restraint using a full-scale rule of reason analysis." Id.

The burden-shifting framework I have adopted does not qualify as a quick-look approach because the plaintiff still maintains the initial burden—establishing anticompetitive effects through market power and evidence of a large reverse payment. While Defendants argue that bearing the burden of justifying the reverse payments will make parties less likely to settle complex patent litigation, the Supreme Court has considered this argument and rejected it. See Actavis, 133 S. Ct. at 2237 ("the fact that a large, unjustified reverse payment risks antitrust liability does not prevent litigating parties from settling their lawsuit").

B. What Constitutes a Large Payment?

Actavis did not identify any specific formula for determining whether a reverse payment is sufficiently large. Defendants argue that the appropriate consideration is whether the unexplained portion of the payment is large in comparison to the brand manufacturer's expected monopoly profits in the absence of generic competition. However, Defendants do not indicate what percentage of the expected monopoly profits would meet this threshold. Plaintiffs respond that a reverse payment is sufficiently large if it exceeds saved litigation costs and a reasonable jury could find that the payment was significant enough to induce a generic challenger to abandon its patent claim. For the following reasons, I find that Actavis supports Plaintiffs' approach.

First, Actavis specifically instructs that an appropriate benchmark for the size of a reverse payment is "its scale in relation to the payor's anticipated future litigation costs[.]" Id. at 2237. Examining the record before me, I note that Plaintiffs have presented evidence that the average litigation costs for patent cases with more than $25 million at stake are approximately $5.5 million per party, which could establish that Cephalon saved approximately $22 million in litigation expenses. (Noll Exp. Rep., May 26, 2011, ¶ 31.) Additionally, the Ranbaxy, Mylan and Barr Agreements specifically identified amounts paid for saved litigation costs—$2 million to each party, for a total of $6 million. (Pls.' Comb. SUF ¶¶ 163, 173, 187.) This number reaches approximately $13 million if one includes the payments made to Teva for avoidance of litigation costs in the United Kingdom. (FTC SUF ¶¶ 119-21.) Nonetheless, by any of these measures, the total amounts paid by Cephalon to each of the Generic Defendants greatly exceed saved litigation expenses, thus satisfying the first part of the "large" standard.

Regarding the "inducement" prong, Actavis instructs that "there are indications that patentees sometimes pay a generic challenger a sum even larger than what the generic would gain in profits if it won the paragraph IV litigation and entered the market[,]" which "cannot in every case be supported by traditional settlement considerations." Actavis, 133 S. Ct. at 2234-35. This statement seems to contradict Defendants' argument that the brand manufacturer's expected monopoly profits constitutes the appropriate benchmark. As Actavis explains, the relevant inquiry is what would induce the generic to stay off of the market. Id. at 2235. A reasonable jury could find that a reverse payment to a generic manufacturer that comes close to or exceeds the expected profits to be earned by prevailing in the patent litigation could induce a generic manufacturer to forfeit its claim. See Herbert Hovenkamp, *Anticompetitive Patent Settlements and the Supreme Court's Actavis Decision*, 15 Minn. J. L. Sci. & Tech. 3, 12 (Winter

2014) ("Even if the generic believes there is a 100% likelihood that the patent will be found invalid, it may still be more valuable for the generic to share the monopoly returns").

Applying these principles, I find that the evidence presented by Plaintiffs on this issue creates a genuine dispute of material fact as to whether the reverse payment was large enough to induce the Generic Defendants to stay off of the market. Several of Plaintiffs' experts have weighed in on the profits that the Generic Defendants could have expected to earn had they released a generic modafinil product as opposed to settling with Cephalon, and have concluded that the amounts paid to these Generic Defendants have come close to, or in some instances, greatly exceeded the profits they could have expected to earn through an at-risk launch. (See e.g., Hartman Exp. Rep., Dec. 20, 2013, ¶¶ 58-61; Elhauge Exp. Rep., Apr. 26, 2011, ¶¶ 17-18; Noll Exp. Rep., May 26, 2011, ¶ 200.)[13]

Ranbaxy, the recipient of the smallest payment, also argues that the $27 million it received is less than its expected profits from an at-risk launch, pointing to calculations of some of Plaintiffs' experts. However, Plaintiffs have provided internal Ranbaxy documents and deposition testimony indicating that Ranbaxy valued its market opportunity for generic modafinil as having a net present value ("NPV") between $7.6 and $8.8 million over a five-and-a-half year period. (Letter Decl., Ex. 114; Fabiano Dep., pp. 194-200.) By contrast, Ranbaxy projected the NPV of the expected payments from Cephalon under the settlement agreements at over $10 million. (Letter Decl., Ex. 116; Fabiano Dep., pp. 194-200.) Evidence of Ranbaxy's evaluation

[13] I recognize that Plaintiffs' experts Hartman, Noll and Elhauge are the subject of Daubert motions filed by Defendants (see "Joint Motion to Exclude Damages Opinions of Plaintiffs' Experts Drs. Hartman, Leffler, Leitzinger and Noll"; "Defendants' Motion to Exclude the Testimony of Plaintiffs' Proposed Economic Experts"). These motions do not assert that Plaintiffs' experts understate the Generic Defendants' expected profits—in fact, the motion to exclude these experts' damages opinions appears to argue the opposite. Therefore, I will consider these figures in deciding the summary judgment motions currently before me.

of the two options before it, and its determination that the settlement payments from Cephalon had greater value, creates a genuine dispute of material fact as to whether the $27 million payment to Ranbaxy was sufficiently large to induce it to abandon the challenge to the RE '516 patent.

I further disagree with Defendants' contention that only the unexplained portion of a reverse payment should be considered in assessing whether a reverse payment is large. As previously discussed, Defendants, not Plaintiffs, bear the burden of explaining the payments. Whether or not the payment constitutes "fair value for services" or some other legitimate justification will be in contention in nearly every case, with plaintiffs arguing that most, if it not all, of the payment is mere pretext for a payment for delay. Therefore, I find that the entirety of the reverse payment should be considered in determining whether the payment is large under Actavis.

Plaintiffs have presented sufficient evidence to create a genuine dispute as to whether the reverse payments exceeded litigation costs and were large enough to induce the Generic Defendants to drop their patent challenge and stay off of the market. As Defendants have not challenged Plaintiffs' ability to demonstrate market power,[14] Plaintiffs have presented sufficient evidence to meet their initial burden under the rule of reason.

C. Plaintiffs' Evidence to Rebut Defendants' Procompetitive Justifications

Defendants stress that the money Cephalon provided to the Generic Defendants was for avoidance of litigation expenses and fair value for services provided. See Actavis, 133 S. Ct. at 2236 (where reverse payments reflect "traditional settlement considerations, such as avoided

[14] Similarly, Defendants have not challenged the Plaintiffs' ability to demonstrate monopoly power on its conspiracy to monopolize claims. See Eastman Kodak Co. v. Image Tech. Svc., Inc., 504 U.S. 451, 481 (1992) (a plaintiff asserting a claim for monopolization must establish (1) monopoly power in the relevant market; and (2) anticompetitive conduct).

litigation costs or fair value for services, there is not the same concern that a patentee is using its monopoly profits to avoid the risk of patent invalidation or a finding of noninfringement"); (see Snyder Exp. Rep., June 10, 2011, ¶ 185-200; Bell Supp. Exp. Rep., Dec. 20, 2013, ¶¶ 15-39.) Whether Defendants have met that burden is not currently disputed.

Plaintiffs have presented sufficient evidence to rebut Defendants' procompetitive justifications and raise a genuine factual dispute as to whether the payments were reasonably necessary to achieve the procompetitive benefits. A reasonable jury could conclude that the payments were aimed at delaying generic entry and that Defendants' justifications are pretextual.

First, Plaintiffs cite to evidence of Cephalon's internal statements suggesting that it had knowledge of the RE '516 patent's weaknesses. In February 2005, a Cephalon consultant wrote that Provigil "faces the certain prospect of generic competition by June 2006." (FTC SUF, Ex. 15.) Similarly, a publication issued by Cephalon's Executive Vice President and General Counsel shortly after the settlements stated that "[i]n the end, Cephalon was able to secure almost six additional years of exclusivity for PROVIGIL by allowing each generic firm to enter the market three years prior to the expiration of the particle-size patent." (Letter Decl., Ex. 35; see also Id. at Ex. 152 ("The Provigil settlement extends the US period of exclusivity on Provigil").) Given the fact that the RE '516 patent wasn't due to expire until 2015, a jury could conclude that these statements reflected Cephalon's view that its patent was weak. Additionally, the arguments raised by the Generic Defendants in the Paragraph IV litigation largely mirrored the facts that were eventually used to invalidate and render unenforceable the RE '516 patent, demonstrating the Generic Defendants' knowledge of those facts.

Plaintiffs have also produced several experts who will opine that numerous services articulated in the settlement agreements were unnecessary and unwanted. Defendants have

objected to these expert witnesses, arguing that their failure to properly assess the fair market value of the various side-agreements is fatal to their claims. In In re Nexium, the Honorable William G. Young considered a similar argument—that without evidence that the generic had received greater than fair market value for its services, the reverse-payment was per se lawful. Judge Young disagreed with the defendants' position, finding that:

> establishing fair market value is just one of many possible defenses available to a Defendant seeking to demonstrate procompetitive justifications for a reverse payment. Nowhere in Actavis does the Supreme Court suggest that fair market value is a silver bullet against antitrust scrutiny. Neither does the opinion place the initial burden on the Plaintiffs to prove, in their prima facie case, that a transaction was for something other than fair market value.

In re Nexium, 2014 WL 4370333, at *24 (D. Mass. Sept. 4, 2014). I find Judge Young's analysis on this issue to be correct. While evidence that these payments exceed fair value for goods and services would certainly be helpful for Plaintiffs in rebutting Defendants' justifications, I do not find that it is a necessary element of Plaintiffs' claims.[15] See Actavis, 133 S. Ct. at 2237 (the fact that the plaintiff must prove its case does not require it to "refute every possible pro-defense theory"). Plaintiffs have provided significant direct and circumstantial evidence that, if believed, could lead a reasonable jury to conclude that the side-deals between Cephalon and the Generic Defendants were simply a means of providing payments for delay.[16]

[15] I also disagree with Defendants' contention that Plaintiffs must establish that the value Cephalon received from the goods and services was grossly inadequate, and the transactions were a complete sham, in order to demonstrate that the reverse payments were unjustified. Cephalon, Barr and Teva urge that American Motor Inns, Inc. v. Holiday Inns, Inc., 521 F.2d 1230 (3d Cir. 1975) prohibits the "second guessing" of complex business agreements. I do not read American Motors that expansively. See id. at 1248-50 (finding that the availability of alternative means of achieving a defendant's stated business purpose does not automatically render the agreement unlawful; rather, courts should determine whether the restriction was "fairly necessary in the circumstances of the particular case").

[16] This evidence distinguishes Plaintiffs' expert reports from the cases cited by Ranbaxy, wherein the plaintiffs relied upon expert opinions that were not based upon facts in the record. See In re

The API supply portions of the settlement agreements also create a factual issue regarding Plaintiff's ability to rebut Defendants procompetitive justification. Plaintiffs have pointed to evidence demonstrating that at the time the API agreements were reached, Cephalon already had an API agreement with Helsinn in Switzerland, as well as its own internal supply held in France. At the time that the API-supply agreements were made with Teva, Ranbaxy and ChemAgis, Cephalon was obtaining modafinil API from Helsinn for under $200/kg. The API-supply agreements called for Cephalon to pay Teva, Ranbaxy and ChemAgis two to three times that amount. (Pls.' Comb. SUF ¶¶ 206, 213-19, 221.)

Plaintiffs also point to evidence demonstrating that Cephalon disregarded its corporate "guiding principles" and due diligence checklist for obtaining API suppliers in entering into these agreements. The amount of modafinil API that Cephalon agreed to purchase from the Generic Defendants far exceeded Cephalon's projected API requirements, and internal documents and deposition testimony from Cephalon indicate that the agreement with Helsinn and Cephalon's internal supply would have met Cephalon's modafinil API needs. One Cephalon executive characterized the API side deals as "a supply chain nightmare," and the supply agreement with Ranbaxy was terminated in 2009 in exchange for a buyout of $13.5 million. (Id. at ¶¶ 205, 207-12, 226-30, 232, 237-38, 252, 261.) Plaintiffs have also presented expert evidence suggesting that these API agreements were outside of the industry's norms, that Cephalon had no need for the additional API, and the amounts paid by Cephalon were far in

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Baby Food Antitrust Litig., 166 F.3d 112, 135 (3d Cir. 1999) (quoting Brooke Grp. Ltd. v. Brown & Williamson Tobacco Corp., 509 U.S. 209, 242 (1993)) ("When an expert opinion is not supported by sufficient facts to validate it in the eyes of the law, or when indisputable record facts contradict or otherwise render the opinion unreasonable, it cannot support a jury's verdict"); Advo, Inc. v. Phila. Newspapers, Inc., 51 F.3d 1191, 1198 (3d Cir. 1995) (finding that expert opinions could not subvert summary judgment in predatory pricing case where there was no direct evidence of predatory pricing).

excess of the amounts in which it could have received API from Helsinn or other suppliers. (McCool Exp. Rep., Apr. 25, 2011, pp. 29-35.)

As to the IP rights, Plaintiffs present evidence that Cephalon was aware of other IP involving modafinil and had never sought to license it, nor indicated that there was any infringement risk. To the contrary, in August of 2005, just months prior to the settlement agreements, Cephalon's chief patent counsel stated "[w]e know the patent landscape for modafinil and formulations of modafinil and are not aware of any potential infringement problems." (Pls.' Comb. SUF ¶¶ 290-91, 293, 296.) A few months later, Defendants agreed to pay up to $131 million for this same IP. Plaintiffs have further presented expert opinions that Cephalon went outside industry norms and failed to conduct due diligence prior to licensing the Generic Defendants' IP. (Bazerman Exp. Rep., Apr. 21, 2011, ¶ 21.)

Finally, with regard to the product development agreements between Cephalon and Mylan, Plaintiffs point to evidence demonstrating that Cephalon had not approached Mylan about the development of these products prior to the modafinil settlement. According to a Mylan financial projection prior to the settlement agreement, Mylan predicted that the option agreement for the fentanyl patch was worth $41.8 million to Mylan and negative $11.6 million to Cephalon. When Cephalon began conducting due diligence on the fentanyl product development agreement, it also determined that it likely had a negative net present value for Cephalon. Despite these findings, Cephalon exercised its option for a Collaboration Agreement in June 2006. Cephalon later terminated both of the development agreements in January 2009, after paying Mylan tens of millions of dollars. (Pls.' Comb. SUF ¶¶ 377, 380, 382, 384, 386, 388.)

While I fully appreciate that Cephalon will have vigorous procompetitive responses to all of this evidence, a jury presented with these facts could find that the side agreements between

Cephalon and the Generic Defendants were a means of disguising payments for delay and/or inducing the Generic Defendants to stay off of the market. Therefore, while Defendants bear the burden of justifying the reverse payments as procompetitive, Plaintiffs have pointed to sufficient evidence to rebut these procompetitive purposes so to create a genuine dispute of material fact.

D. Ranbaxy's Causation Argument

Ranbaxy separately argues that, even if Plaintiffs could establish that Ranbaxy received a large and unexplained payment from Cephalon, Plaintiffs have not provided any evidence that the Ranbaxy-Cephalon settlement caused Ranbaxy to delay launching its generic modafinil product. More specifically, Ranbaxy asserts that all evidence indicates that it would not have launched "at risk," even if it had not settled with Cephalon.

Ranbaxy's position essentially relates to antitrust injury, which has been described as follows by the Supreme Court:

> Plaintiffs must prove antitrust injury, which is to say injury of the type the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful. The injury should reflect the anticompetitive effect either of the violation or of anticompetitive acts made possible by the violation.

Brunswick Corp. v. Pueblo Bowl-O-Mat, Inc., 429 U.S. 477, 489 (1977). To determine whether the injury flowed from an illegal restraint on competition, the court "must examine the causal connection between the purportedly unlawful conduct and the injury." City of Pittsburgh v. W. Penn Power Co., 147 F.3d 256, 265 (3d Cir. 1998).

In support of its argument, Ranbaxy points to evidence that it had attempted to launch a generic product at risk in 2005, had been unsuccessful, and was dealing with the financial ramifications of that attempt at the time of the Cephalon settlement. (Ranbaxy SUF ¶¶ 17-19.) Ranbaxy further points to a statement from its Senior Vice President & Regional Director for

North America, stating that there was no way that Ranbaxy would have launched generic modafinil at risk. (Id. at ¶ 16.)

Plaintiffs respond that genuine disputes of material fact exist as to whether Ranbaxy planned to launch at risk prior to the settlement with Cephalon. For example, Ranbaxy internal documents from April 12, 2005 identified June 2006 as the "likely launch date" for Ranbaxy's generic modafinil product. At deposition, Ranbaxy representatives also explained that after reviewing some of these documents, it appeared Ranbaxy had begun taking steps toward an at-risk launch as of November 2005. Emails and deposition testimony from Ranbaxy representatives indicate that Ranbaxy was planning to place an order for a "launch quantity" of modafinil API in December 2005, but ultimately did not because of the settlement with Cephalon. (Pls.' Comb. SUF ¶¶ 121-25.)

Given this conflicting evidence, a genuine dispute of material fact exists as to whether Ranbaxy would have launched at risk, and thus, whether Plaintiffs are able to establish causation as to Ranbaxy. See In re Neurontin Antitrust Litig., 2013 WL 4042460, at *10 (D.N.J. Aug. 8, 2013) (citing Rivas v. City of Passaic, 365 F.3d 181, 193 (3d Cir. 2004)) ("causation is a factual issue for the jury").

IV. CONCLUSION

For the reasons stated above, I find that a plaintiff challenging a reverse-payment settlement as anticompetitive under Actavis must demonstrate anticompetitive effects, including a large reverse payment, under the first step of the rule of reason. The defendant then bears the burden of explaining or justifying the payment as procompetitive. If the plaintiff presents evidence to raise a factual dispute as to defendant's proffered justifications, the fact-finder will

weigh all relevant information and determine whether the settlement was, on balance, unreasonable, as in other rule of reason cases.

Plaintiffs have presented sufficient evidence to meet their burden under the rule of reason to survive summary judgment. An appropriate Order follows.